DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2005

Swissray Medical AG
% Mr. John Monahan
QA Manager
Swissray Int., Inc.
1180 Mclester Street, Unit #2
ELIZABETH NJ 07201

Re: K050718
Trade/Device Name: ddRCombi Trauma
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB and KPR
Dated: March 16, 2005
Received: April 6, 2005

Dear Mr. Monahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (K) Number: **K050718**

Device name : ***ddR*Combi Trauma**

Indication for Use

The Swissray Medical AG Direct Digital X-ray Radiography diagnostic system class II (stationary) ***ddR*Combi Trauma** is a further development of the **AddOn Multi System**. This system can be used in a standard X-ray room and suitable for emergency / Trauma X-ray rooms.
The ***ddR*Combi Trauma** is intend for applying general radiography on a patient in a supine, seated or standing position.
With the fix height adjustable patient table and the new flexible detector positioning, the patient must be no more repositioned for the most X-ray applications.

The ***ddR*Combi Trauma** allows the operator a full control of the Patient data, positioning, X-ray parameter (automatic by organ selection or manual settings), exposure control and image quality.
The operator can use the following image control functions without losing the original exposure:

- Brightness, contrast, shape, rotate, zoom, inverse, cut off etc.
- Storage function (PACS, HL 7) included all X-ray parameter and patient information

The ***ddR*Combi Trauma** allows the operator to print images (DICOM format) in background on a laser printer (the most printer suppliers are available) or CD-ROM.
The major system components are:
fix height adjustable patient table, X-ray generator, X-ray tube, Collimator, stand, ceiling suspension, digital AddOn bucky (4 CCD cameras), Image processing software and monitors.

(Please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (DOE)

(Prescription Use) or Over-The Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050718